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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 08/957, 709 | 10/24/97 | HOGREFE | H 1486/41363CP |

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FINNEGAN, HENDERSON, FARABOW, GARRETT
& DUNNER, L.L.P.
1300 I STREET N.W.
WASHINGTON DC 20005

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| EXAMINER | |
| HOUTTEMAN, S | |
| ART UNIT | PAPER NUMBER |
| 1655 | /4 |

DATE MAILED: 11/23/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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|------------------------------|--------------------------------------|---------------------------------------|
| Office Action Summary | Application No. 08/957,709 | Applicant(s) Hogrefe et al. |
| | Examiner Scott Houtteman | Group Art Unit 1655 |

Responsive to communication(s) filed on Sep 8, 1999

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

- Claim(s) 1-23, 30-39, 45, 46, 59-66, 77-80, 85, 87-92, 95, and 96 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- Claim(s) 1-23, 30-39, 45, 46, 59-66, 77-80, 85, 87-92, 95, and 96 is/are rejected.
- Claim(s) _____ is/are objected to.
- Claims _____ are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All Some* None of the CERTIFIED copies of the priority documents have been received.
- received in Application No. (Series Code/Serial Number) _____.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- Notice of References Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

1. Applicant's response, filed 3/2/99, has been carefully considered with the following effect:

The objections and rejections of paragraphs 3, 4A-C, 5, 7 and 8, Office action mailed 3/2/99, have been maintained.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-23, 30-39, 45, 46, 59-66, 77-80, 85 and 87-92, 95 and 96 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-39, 45 and 46 of copending Application No. 08/822,774.

Applicant has not taken this opportunity to argue this rejection. Any argument applicant has to this rejection should have been made at this time. This rejection is held in abeyance at applicant's request. However, applicant will not be allowed to argue points that could have been argued at this time.

4. Claims 1-23, 30-39, 45, 46, 59-66, 77-80, 85, 87-92, 95 and 96 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1-23, 30-39, 45, 46, 59-66, 77-80, 85, 87-92, 95 and 96 are indefinite in the recitation of "polymerase enhancing factor" (PEF) in view of the definition of PEF in the specification, page 5, line 31 to page 6, line 1, for reasons of record.

B. Claims 95 and 96 are indefinite for the reasons stated in the rejection of canceled claims 28 and 29. These claims define a protein in terms of nucleic acid hybridization function. Nucleic acid hybridization is unrelated to protein function. It is unclear how (or why) a protein could be clearly described using nucleic acid hybridization. Applicant has offered no argument to this point but merely canceled the original claims and added new claims having similar characteristics.

C. Claims 1-23, 30-39, 45, 46, 59-66, 77-80, 85 and 87-92, 95 and 96 are indefinite in the recitation of "or analogs thereof," "sequences hybridizable thereto," "degenerate variants thereof" and "wholly or partially synthetic protein," for reasons of record. See, for example newly amended claim 1, line 6.

5. Applicant argues that the skilled artisans are familiar with "mutating, modifying, truncating, or otherwise changing a protein's amino acid sequence and retaining its functional activity."

This argument is not persuasive. It is acknowledged that methods of altering protein structure are known and enabled. The claims, however, are not drawn to these methods of "mutating, modifying, truncating, or otherwise changing a protein's amino acid sequence and retaining its functional activity." These claims are drawn to the *product* of these methods. Furthermore, since the claims are not limited to any number of mutations, it is unclear how far from the structures explicitly disclosed one can diverge yet still be within the scope of these claims.

Surely, a single conservative amino acid change at the end of a protein is **within** the scope of these claims. Surely, a protein that has had so many mutations that there is no longer any sequence similarity to the claimed protein is **outside** the scope of these claims. The question remains, where, between these two extremes is the **boundary** of these “analog” claims.

Applicant argues the art skilled “understand the scope” and can “determine the scope of what is meant by ‘an analog.’” This argument is not persuasive. The boundary of these claims is unclear. As stated previously, one has no idea about the location of the boundary. Applicant’s arguments have not explained how to find this boundary but merely conclude, without substantiation, that the skilled artisan could find this boundary.

Applicant argues that the amendments to claims 12 and 17 render the rejection concerning “degenerate variants of the recited sequences” moot. This argument is not persuasive. As stated previously, the specification definition of PEF remains and contains the “analog thereof” phrase. Thus, where ever the claims recite PEF, the definition, “analog thereof” is read into the claims. Also, the claims still contain the indefinite “or analogs thereof” language

6. Claims 1-23, 30-39, 45, 46, 59-66, 77-80, 85 and 87-92, 95 and 96 are rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling for the specific *Pyrococcus furiosus* protein isolated as set forth in the specification, defined either by its denatured molecular weight or by its unique DNA sequence, for reasons of record.

Applicant argues that “techniques analogous to the specific examples involving *Pyrococcus furiosus* could be used, that the examiner has failed to establish that the specification is not enabling.

These arguments are not persuasive. The facts in this case are closely analogous to *In re Vaeck* (20 USPQ2d 1238). In *Vaeck*, as here, applicant is claiming coverage for an entire genus. Here the claims are even broader, including “analog” of proteins isolated within this species. Also, in *Vaeck* the organisms of the genus were merely proposed as a host of a vector. Here, the organisms of the genus must be used for the much more difficult task of cloning a novel gene.

There is a high level of unpredictability about the claimed genus which is large, diverse and relatively poorly studied. In light of the limited guidance in the specification and the unpredictability in this particular art, it would have required undue experimentation to practice the broad scope of the claimed invention. Applicant’s argument merely lists some of the experimentation necessary but does not take into account the unpredictability of the art and the lack of specific guidance with respect to the other organisms in the genus.

7. Claims 1-23, 30-39, 45, 46, 59-66, 77-80, 85 and 87-92, 95 and 96 rejected under 35 U.S.C. § 103(a) as being unpatentable over Sorge et al., US Pat. 5,556,772; 9/1996, filed 2/1994 (Sorge) for reasons or record.

8. Applicant argues that Sorge does not discuss factors that enhance polymerase activity, that the property in Sorge is “unknown but allegedly implicit.” This argument is not persuasive.

The rejection pointed out explicitly where Sorge discusses factors that enhance polymerase activity. The argument does not discuss this portion of the rejection.

Applicant's remaining arguments depend upon Sorge allegedly not teaching or suggesting polymerase enhancing factors.

Sorge teaches polymerase enhancing factors as explained above. These arguments are not persuasive for the reasons above.

9. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

10. Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Technology Center 1600 Fax numbers are (703) 305-3014 and 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott Houtteman whose telephone number is (703) 308-3885. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday from 8:30 AM - 3:30 PM. The examiner can also be reached on alternate Wednesdays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

Scott Houtteman
November 22, 1999



SCOTT W. HOUTTEMAN
PRIMARY EXAMINER